

### III. Remarks

As agreed in the interview, this response briefly addresses only those aspects of the action that needed clarification consistent with the interview discussion. This included: §112 concerns involving all preambles; an antecedent basis concern; concerns regarding the thawing and isolating steps in claim 38; clarity concerns regarding the "at least some" language; reference to the time limits, protective component, and number values included in certain claims; and finally some discussion regarding §103 questions over the clause regarding the lack of protective compounds. As mentioned in the interview, should any other aspects remain at issue or additional information be desired, it is again requested that for efficiency the examiner contact the undersigned by telephone so that any remaining informalities maybe dealt with as efficiently as possible through a Supplemental Response or Examiner's Amendment as agreed.

As discussed in the interview, the examiner suggested that the claims might be more clear if the preambles were changed from a "method of freezing" to a "method of cryopreserving" and the step of freezing in claim 38 be omitted to be pursued in a divisional application or the like. This suggestion has been following by the above amendments.

Similarly, for clarity reasons the examiner recommended the elimination of the step of "isolating at least some of said sex-selected sperm cells" in claim 38. This has been accomplished as suggested.

In addition, the examiner pointed out that the reference in claim 42 to "said species of said male mammal" lacked proper antecedent basis. This has been corrected through an amendment of claim 38 to reference "a species of a male mammal".

In certain claims, the examiner felt that the commentary to "at least some" of the specified cells or the like was potentially confusing. Such language has been eliminated from claims 38, 40, 41, 43, 44, and 60-64 as suggested.

The examiner also requested highlighting the specification's references discussing the time limits, the protective compounds, and certain number values in the specification.

Claim 63 as amended mentions the aspect of equilibrating for period of about 1 hour to about 18 hours. This aspect is discussed in the specification on page 17 beginning at line 6.

Claim 38 references the aspect of sorting the sperm cells without the presence of the protective compounds in seminal plasma. This aspect and one or more of the specific types of substances effecting protection are mentioned in the specification at page 2, beginning at line 5; at page 7, beginning at line 26; at page 9, beginning at line 1; at page 9, beginning at line 17; at page 16, beginning at line 15; and at page 23, beginning at line 4. Of these, it may be noted that various substances used in extenders and as cryoprotectants are also mentioned.

Claim 38 also references the aspect of 5 million per milliliter of extender to at least about 10 million per milliliter of extender. This aspect and one or more of these specific values are mentioned in the specification at page 19, beginning at line 16; at page 20, beginning at line 11; at page 21, beginning at line 7; at page 22, beginning at line 8; at page 22, beginning at line 18; and at page 23, beginning at line 1. Of particular note and as discussed in the interview, the values and results shown in Table 1 on page 21 and to some degree in Table 2 on page 19 highlight how the claimed ranges show significant in the data. Specifically referencing table 1, it can be seen how the results increase to a more consistent value when the dilution is established at values of at least about 5 million per milliliter of extender to at least about 10 million per milliliter of extender.

Claim 43 references the aspect of utilizing between about 1,000,000 million and about 25,000,000 equine sperm. Various dosages and amounts are discussed in the specification. The volume of the straws used for insemination is also mentioned as both 0.25 ml and 0.50 ml at page 17 beginning on line 30 among other locations. Applying the extension mentioned in the specification at page 11 beginning at line 26 and at page 22 beginning at line 8 with these volumes of straws, it can be understood that sperm dosages of  $1,250,000 (2.5 \times 10^6/\text{ml}$  in a 0.50 ml straw) and  $25,000,000 (50 \times 10^6/\text{ml}$  in a 0.50 ml straw) were used. Further, at page 47 beginning at line 17, at page 48 beginning at line 5, at page 51 beginning at line 17, at page 52 beginning at line 25, and also at page 53 beginning at line 4, the use of  $1,000,000 (1 \times 10^6)$  sperm is explicitly mentioned.

Finally, the examiner requested some commentary regarding the aspects of the cryoprotective compounds as not being present in the Spaulding reference. The Spaulding reference proposes the use of antibodies as a vaccine or to achieve sex selection. Besides the fact that this reference has apparently not been shown to actually be achievable - and for convenience only -- the claims are at this stage distinguished from the Spaulding reference

through their inclusion of the element of sorting the sperm cells without the presence of protective compounds in seminal plasma and suspending at dilutions of at least about 5 million per milliliter of extender to at least about 10 million per milliliter of extender. As mentioned in the specification and above, sorting without the presence of protective compounds is a feature that occurs when flow cytometry is used to achieve sex sorting. This technique has been shown to work and is now in practice and is even mentioned in the Spaulding reference (albeit not at the dilutions now set forth). In using this technique, the sperm are stripped of their natural protective compounds and thus are subjected to a more stressful environment. This aspect is not present when using the antibody approach of the Spaulding reference whether it be the immunization of the female (as proposed in Spaulding at column 4, line 43) or for example when binding monoclonal and polyclonal antibodies for sex-enriched semen samples (as proposed in Spaulding at column 4, line 50). Thus, the reference does not address the aspects claims and the section 103 concerns are not believed appropriate.

The amendments submitted herein should be understood to be made as a practicality only, and should not to be construed as creating any situation of file wrapper estoppel or the like as all rights are expressly reserved and may be pursued in this or other applications, such as divisionals, continuations, or continuations-in-part if desired. Relatedly, it should be understood that the amendments made herein are made for tangential issues of clarity and as a matter of the Office's convenience or expedience only. The amendments should not be interpreted as an action that in any way surrenders a particular equivalency, surrenders any right to patent coverage, or otherwise limits any rights which the Applicant may now or hereafter assert. It should be understood that, unless and to the extent deemed broadened by this amendment, and even as amended, the Applicant expressly reserves all rights, including but not limited to: all rights to maintain the scope of literal coverage with respect to any element as may have existed under the language previously presented, all rights to maintain the scope of equivalency coverage as may have existed under the language previously presented, and all rights to re-present the prior language at any time in this or any subsequent application. To the extent currently foreseeable, no change or reduction in direct or equivalency coverage is believed to exist, and no change or reduction in direct or equivalency coverage is intended through the presentation of this amendment.

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The Applicant believes all concerns raised in the August 26, 2004 office action have been addressed and that all claims remaining in the case – claims 38, 39, 42-54, 57-59, 63, and 64 – are in condition for allowance. Reconsideration and allowance of these remaining claims is respectfully requested at the Examiner's earliest convenience. Finally, should the Examiner have any remaining questions or disagree with any of Applicant's explanations, it is requested that the Examiner contact the undersigned by telephone in order to expedite the processing of this application as discussed in the interview.

Dated this 28<sup>th</sup> day of February, 2005.

Respectfully submitted,  
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